

Report of CDC IRB “ ”
CDC Protocol #_____, “ ”
May 23, 2003

General Comments and IRB Actions

The convened board of IRB “ _ ” reviewed your request (for new protocol approval/to continue/ to amend protocol #_____. We have determined that the study (still) involves (greater than/no more than) minimal risk to subjects. Upon receipt of satisfactory responses to the following issues and concerns, and upon receipt of a clean copy/ies of the revised protocol/consent form(s)/assent form(s)/questionnaire(s), the IRB will approve (continuation of your/your amended/ your new) protocol.

Protocol Issues

Response Required, Action Required

- 1)
- 2)
- 3)

Response Required, Action Optional

- 1)
- 2)
- 3)

Of Note - No Response or Action Required

Consent Form Issues

Response Required, Action Required

- 1)
- 2)
- 3)

Response Required, Action Optional

- 1)
- 2)
- 3)

Of Note - No Response or Action Required

Protocol # _____
Page 2 of 2

Addenda Issues (Questionnaires, brochures, posters, etc.)

Response Required, Action Required

- 1)
- 2)
- 3)

Response Required, Action Optional

- 1)
- 2)
- 3)

Of Note - No Response or Action Required

End of Report